A2 cont'd Subt

11. (Once Amended ) The soluble film preparation according to claim 10, in which the compound is nilvadipine, the additional edible polymer is hydroxypropyl cellulose, and the starch syrup is reducing maltose starch syrup.

Please add the following new claims:

A3

12. A soluble film preparation comprising a drug, an edible polymer and a saccharide selected from the group consisting of: erythritol, pentitol, hexitol, aldose, ketose, xylitol, mannitol, reducing maltose starch syrup, glucose, fructose, maltose, lactose, sucrose, and starch syrup.

REMARKS

In the Office Action dated December 17, 2001, claims 1-11 are pending in the present application, and all of claims 1-11 stand rejected. Claims 1-11 have been amended to further clarify the subject matter of the invention. New claim 12 has been added. No new matter has been added by virtue of the amendments or new claims because they are supported in the specification. Support for new claim 12 is found on, e.g., on page 6, line 20 through page 7, line 3.

Applicants respectfully request reconsideration of the application in light of the above amendments and the following discussion.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Claims 1-11 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to remove indefinite terminology. Applicants respectfully request the removal of this rejection.

Claims 1-5 stand rejected under 35 U.S.C. §102(b) as anticipated by Iwamura, *et al.* Applicants respectfully traverse this rejection. The cited reference does not disclose or suggest the presently claimed composition. The cited reference does not teach the presently claimed soluble film preparation.

The claims as amended are to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide.

The Iwamura reference does not teach the inclusion of either a monosaccharide or an oligosaccharide in such a preparation. Iwamura, *et al.* teaches a sheet-like preparation comprising a drug, gelatin or agar, gluten, a carboxyvinyl polymer, a polyhydric alcohol, a gum, a wax, and water.

The present specification describes a soluble film preparation comprising a drug, an edible polymer and either a monosaccharide or an oligosaccharide.

Applicants respectfully request reconsideration and withdrawal of the rejection.

New claim 12 is also not anticipated by the Iwamura reference because the reference does not teach any of the saccharides as a component in the soluble film preparations recited in the new claim.

Thus, all the claims are allowable over this reference.

Claims 1-5 stand rejected under 35 U.S.C. §103(a) as obvious over Iwamura *et al.* and Miranda, *et al.* Applicants respectfully traverse this rejection. The cited reference does not teach the presently claimed soluble film preparation.

Miranda *et al.* discloses a pressure-adhesive composition for transdermal drug delivery in which the drug is delivered from the pressure-sensitive adhesive composition and through dermis when the pressure-sensitive adhesive composition is in contact with human skin (see col. 2, lines 51-57).

The Miranda reference does not disclose the inclusion of saccharides in the disclosed transdermal drug delivery compositions. Further, the compositions taught by Miranda, *et al.* are concerned with delivery of drugs through the skin. There is no teaching in Miranda to combine the reference with Iwamura, *et al.* that discloses oral drug delivery compounds despite that polyvinyl pyrrolidone (PVP) may be included as a component in either of the compositions apparently taught by Miranda, *et al.* and Iwamura, *et al.*

The claims as amended are to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide.

In view of the above discussion and amendment, it is respectfully submitted that the present application is in condition for allowance. Therefore, an early reconsideration and allowance are respectfully requested.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

Date: March 18, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Once Amended) A ~~rapidly~~ soluble film preparation ~~mainly~~ comprising a drug, an edible polymer and a ~~saccharide~~ monosaccharide or an oligosaccharide.

2. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 1, in which the content of the drug is from 0.01 to 50% by weight, that of the edible polymer is from 20 to 90% by weight, and that of the ~~saccharide~~ monosaccharide or the oligosaccharide is from 1 to 50% by weight.

3. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 1, in which the drug is a compound which can be enhanced in internal absorption by the conversion to a solid solution.

4. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 3, in which the compound is nilvadipine.

5. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 1, in which the edible polymer is one selected from the group consisting of synthetic polymers, cellulose derivatives and natural polymers.

6. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 1 or 5, in which the edible polymer is at least one selected from the group consisting of poly(vinylpyrrolidone), hydroxypropyl methyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyethyl cellulose and ethyl cellulose.

~~7. The rapidly soluble film preparation according to claim 1 or 2, in which the saccharide is one selected from the group consisting of monosaccharides, sugar alcohols and oligosaccharides.~~

8. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim ~~7~~1, in which the oligosaccharide is starch syrup.

9. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 8, in which the starch syrup is reducing maltose starch syrup.

10. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 1, in which the drug is a compound which can be enhanced in internal absorption by the conversion to a solid solution, the edible polymer is one or more of poly(vinylpyrrolidone) and hydroxypropyl cellulose, and an additional edible polymer, and the ~~saccharide~~ oligosaccharide is starch syrup~~,~~.

11. (Once Amended ) The ~~rapidly~~ soluble film preparation according to claim 10, in which the compound is nilvadipine, the additional edible polymer is hydroxypropyl cellulose, and the starch syrup is reducing maltose starch syrup.

Please add the following new claims

12. A soluble film preparation ~~mainly~~ comprising a drug, an edible polymer and a saccharide selected from the group consisting of: erythritol, pentitol, hexitol, aldose, ketose, xylitol, mannitol, reducing maltose starch syrup, glucose, fructose, maltose, lactose, sucrose, and starch syrup.